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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,786	07/12/2001	Edward F. Patz JR.	DUKE-227	6628

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EXAMINER
DAVIS, DEBORAH A

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/26/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/902,786	PATZ ET AL.	
	Examiner	Art Unit	
	Deborah A Davis	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,6,11 and 18* is/are pending in the application.

4a) Of the above claim(s) *11 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicants' response to the Office Action mailed December 16, 2002 in Paper #6 is acknowledged. Currently, claims 1, and 5-6 are under consideration. Claims 2-4, 7-10 and 12-17 are cancelled. Claims 11 and 18 are drawn to non-elected subject matter.

Election/Restrictions

2. Claim 18 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: A protein biomarker is a product claim that is independent from the apparatus or system of the instant elected invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 18 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 11 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 11 recites the limitation "comprehensive protein profile" is vague because it is unclear as to what this means.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 5-6 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Yates et al (USP#5,538,897).

Yates et al teaches the use of mass spectrometry fragmentation patterns of peptides to identify amino acid sequences in databases. A peptide is analyzed by tandem mass spectrometer to yield a peptide fragment mass spectrum. A protein sequence database or a nucleotide sequence database is used to predict one or more fragment spectra for comparison with the fragment spectrum, as recited in claims 1 and 4 (see abstract). A fractionation unit such as gel filtration chromatography and/or high performance liquid chromatography (HPLC) is used to separate the proteins before being introduced to mass spectrometer (col. 2, lines 51-55). The proteins are separated into fragments to be analyzed by mass spectrometer (col. 2, lines 65-67). The present invention can be used in connection with diagnostic applications such as some forms of cancer, genetic disease and cystic fibrosis (col. 17, lines 62-67 and col. 18, lines 25-38). According to the definition of Neural Network in the specification, Yates et al describes such a system that provides a protein sequence database that is used to predict one or

more fragment spectra for comparison with derived fragment spectrum. The various predicted mass spectra are compared to the experimentally derived fragment spectrum using a "closeness-of-fit measure" preferable calculated with a two-step process, including a calculation of a preliminary score and, for the highest scoring predicted spectra, calculation of a correlation function as recited in claim 5 (col. 5, lines 1-30, col. 6, lines 38-55 and Figures 6A-6E). The protein data base system assigns peak intensities values to each fragment, which values include the predicted mass spectra and the experimentally-derived fragment spectrum as recited in claim 6 (col. 5, lines 53-67). With respect to the new limitations cited in claim 1 of a protein fractionation unit that separates a protein content of at least two tissue samples, one of a normal cell and the other a tumor cell and comparing the two is considered intended use and will not be given patenable weight.

Response to Arguments

8. Applicant's arguments filed June 16, 2003 have been fully considered but they are not persuasive. Applicant's argument that Yates et al does not teach that his system may be used in diagnostic applications such as cancer biomarkers is not found persuasive because these limitations are intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it

meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In the instant case, Yates et al has a system that has a protein fractionation unit, a mass spectrometer, a protein data processing unit, and a database, therefore Yates et al's system can inherently perform the intended use of applicant's invention. Yates et al teaches that his system can be used in connection with diagnostic applications such as some forms of cancer, genetic disease and cystic fibrosis (col. 17, lines 62-67 and col. 18, lines 25-38). Yates et al believe that the present invention can be used with any peptide (column 18, lines 57-58). Applicant's argument that the instant invention is able to compare protein profiles from at least two samples from the same patient is not found persuasive because this is also intended use. Therefore it is the Examiners position that Yates et al anticipate the instant invention.

Conclusion

9. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

Deborah A. Davis
CM1, 7D16
August 21, 2003

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

08/22/03